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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. **Ulrich Schubert** 151.2-US-WO 01/14/2002 5585 09/913,927 EXAMINER 22462 7590 02/13/2004 **GATES & COOPER LLP** MOSHER, MARY **HOWARD HUGHES CENTER** ART UNIT PAPER NUMBER 6701 CENTER DRIVE WEST, SUITE 1050 LOS ANGELES, CA 90045 1648

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)
	09/913,927	SCHUBERT ET AL.
	Examiner	Art Unit
	Mary E. Mosher, Ph.D.	1648
All participants (applicant, applicant's representative, PTO personnel):		
(1) Mary E. Mosher, Ph.D.	(3)	
(2) Karen Canady.	(4)	
Date of Interview: 11 February 2004.		
Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant 2)□ applicant's representative]		
Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No. If Yes, brief description:		
Claim(s) discussed: all pending.		
Identification of prior art discussed: All art cited in final rejection.		
Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.		
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: <u>See Continuation Sheet</u> .		
(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)		
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.		
	Many hody MARY E. MOSHER	
PRIMARY EXAMINER GROUP 1800-/6		
Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.	 Examiner's sign	ature, if required

# **Summary of Record of Interview Requirements**

## Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

# Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted.
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed.
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
  - (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

## **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed after final amendment filed 10/27/03. Amendment will not be entered, but discussed in detail what the advisory action would say and what the status of the claims would be if the amendment were entered (e.g. after an RCE). Considering that the amendment was filed within 2 months of final rejection, and PTO has delayed in acting on amendment, MM will delay mailing advisory to permit KC to consult clients and file something without paying for extensions.

Details of discussion: The amendment filed 10/27/2003 will not be entered, because recitation of SEQ 2 and SEQ 3 in the claims necessitates additional search, and the amendment to claims 44-45 necessitates a new 112 2nd rejection of dependent claims 46 and 47.

However, considering the delay in responding to applicants amendment, the examiner will indicate what impact the amendment, if entered, would have on the rejections of record.

The rejection of claims 31, 33, 34, 36, and 38, 44, and 45 under 112, 2nd would be obviated by the amendment; however, claims 46 and 47 would be rejected because "an assay product which comprises an ELISA" is confusing.

The "new matter" rejection of claims 34, 35, 38, and 38, involving "bound to a second molecule comprising a DNA or protein molecule" will be withdrawn, on reconsideration of applicant's arguments in this response and the last response. However, the "new matter" rejection of claims 44-47, involving "bound to a solid substrate", will be maintained.

The "how-to-use" enablement rejection of claims 36-39 would be maintained, because the specification does not teach any use, other than nonenabled methods of body treatment, for the peptides in a pharmaceutical carrier.

The "how-to-use" enablement rejection involving SEQ ID NO:8 and 9 will be maintained. The "how to use" aspect of 112, 1st paragraph refers back to the utility requirement of 35 U.S.C. 101, which requires a substantial, specific, and credible utility for a patentable invention. The asserted uses for epitope mapping and isoelectric focusing are not specific uses for the claimed peptides. The uses taught in the preliminary amendment are not part of the disclosure, since that amendment was denied entry for introducing new matter. The argued uses "for structural analyses using NMR and X-ray crystallography" are seen as merely use in further research.

The amendment would not overcome the 102 rejection based on Azad. The amendment clarifying the claimed "fragments" would overcome the part of the rejection based upon Azad's peptides 2, 3, and 5, but would not overcome the rejection based on Azad's yeast-expressed Vpr protein. Applicant argues that the claims are limited to chemically synthesized product, pointing to specification page 9, lines 22-25, and argue that this product is not taught by the references and has unexpected properties of solubility and stability. The text on specification page 9 is ambiguous, and is not sufficient to definitely limit the claim to a product-by-process. Also, even though Azad made the protein by recombinant expression in yeast, there has been no showing that the identical sequence made by the two processes have different properties. Although yeast (and plant) cells are capable of modifying proteins, for example by glycosylation, the examiner has tried and failed to find any evidence that Vpr is glycosylated when it is expressed in eukaryotic cells. Therefore, there is reason to believe that the products are the same, even when made by different processes. The amendment would not overcome the 102 rejection over Koprowski, for essentially the same reasons.

The amendment would overcome the 102 and 103 rejections over Sette.

The amendment would not overcome the 103 rejection over Weiner, since Weiner clearly suggests a chemically synthesized peptide identical to SEQ ID 5, and applicant's specification does not have any evidence of unexpected properties for SEQ ID 5.